

Medical Necessity Guidelines: Clinical Trials: Routine Costs

Effective: October 21, 2020

Prior Authorization Required If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
<p>Applies to:</p> <p>COMMERCIAL Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617.972.9409 <input checked="" type="checkbox"/> Tufts Health Freedom Plan products; Fax: 617.972.9409 • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>TUFTS HEALTH PUBLIC PLANS Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055 <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404 <input checked="" type="checkbox"/> Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304 <p>*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.</p> <p>SENIOR Products</p> <ul style="list-style-type: none"> • Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List • Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List 	

OVERVIEW

A clinical trial is a prospective biomedical or health-related research study of human subjects designed to test new methods of screening, prevention, diagnosis, or treatment of a disease. These studies are conducted by physicians and other health professionals in a controlled environment to help determine the safety and efficacy of biological products, devices, drugs, medical treatments, procedures, or therapies to improve health.

Clinical trials are conducted in phases that help answer different scientific questions.

- **Phase I trials** test a new drug or treatment for the first time to evaluate safety and identify side effects in a small group of people.
- **Phase II trials** study an experimental drug or treatment to determine its effectiveness and further evaluate safety in a large group of people.
- **Phase III trials** confirm the drug or treatment effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely in larger groups of people.
- **Phase IV trials** are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.⁶

Effective January 1, 2014, in accordance with Section 2709 of the Patient Protection and Affordable Care Act (ACA), Tufts Health Plan will provide coverage for 'routine costs' when a Member is a 'qualified individual' enrolled in an 'approved clinical trial':

- In general, routine patient costs for a qualified individual participating in a qualified clinical trial include all items and services consistent with coverage that a Tufts Health Plan Member would be eligible for if not enrolled in a clinical trial.
- A 'qualified individual' is someone who is eligible to participate in an 'approved clinical trial' according to the trial protocol and either the individual's doctor has concluded that participation is appropriate or the participant provides medical and scientific information establishing that their participation is appropriate.
- An 'approved clinical trial' is a phase I, phase II, phase III or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease

or condition. A life threatening disease or condition is defined as any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

There are several types of clinical trials that are eligible for coverage of routine costs:

1. Trials approved or funded by the:
 - National Institutes of Health (NIH)
 - Centers for Disease Control and Prevention (CDC)
 - Agency for Health Care Research & Quality (AHRQ)
 - Centers for Medicare & Medicaid Services (CMS)
2. Trials approved or funded by the below entities when the trial has been reviewed and approved through a system or peer review that the Secretary of Health and Human Services determines is comparable to the peer review system used by the NIH and assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review:
 - Department of Defense (DoD)
 - Department of Veteran Affairs (VA)
 - Department of Energy (DOE)
3. Trials approved or funded by centers or cooperative groups of the NIH, CDC, AHRQ, CMS, DOD, and/or VA.
4. Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drug Administration.
5. For Massachusetts products under MGL Ch. 175 Section 110L(c) and (d), with respect to Phase II, III, or IV clinical trials only, a trial is approved by a qualified institutional review board (IRB) as defined in the statute.
6. For New Hampshire products, a trial is approved by an institutional review board in New Hampshire that has a multiple assurance contract approved by the Office of Protection from Research Risks of the NIH.

CLINICAL COVERAGE CRITERIA

PRIOR AUTHORIZATION IS NOT REQUIRED: Providers will not routinely be required to submit documentation about the clinical trial to Tufts Health Plan. However, documentation may be requested at any time to confirm that the trial meets current standards referenced below:

Tufts Health Plan will cover routine patient costs when medically necessary and consistent with the Member's benefit if the Member was not participating in a clinical trial.

Routine costs include:

- Items or services typically provided absent a clinical trial (e.g., conventional care)
- Items or services solely for the provision of the investigational item or service that are not statutorily excluded from coverage (e.g. cosmetic surgery)
- Clinical monitoring for the effects of the investigational item or service
- Prevention and management of complications
- Items or services for reasonable and necessary care that may occur from the provision an investigational service or item
- For Massachusetts products only, in addition to the above, pursuant to MGL 175 Section 110L(a)(1), the actual costs of the device or drug when it is not paid for by the manufacturer, distributor, or provider of the drug/device

LIMITATIONS

Routine costs do not include:

- For Massachusetts products: the investigational item, device, or service itself when paid for by the manufacturer, distributor, or provider of the drug/device {MGL 175 Section 110L(a)(1)}
- For Rhode Island products: the investigational item, device, or service is not covered regardless of manufacturer, distributor, or provider of the drug/device payment or nonpayment
- For New Hampshire products: The cost of an investigational new drug or device that is not approved for market for any indication by the FDA. {NH RSA 415:18-I Section I (h) (1)}
- Items and services that are provided solely to satisfy data collection, analysis needs and that are not used in the direct clinical management of the Member
- Any item, service, or cost that is reimbursed or provided by the sponsors of the clinical trial
- Non-health care services that a Member may receive as a result of being enrolled in the qualified clinical trial

- Services or costs that are **not** covered under the Member’s Evidence of Coverage (EOC)

CODES

Table 1 contains modifiers which are item/service specific and constitute medically necessary routine patient care or treatment of complications arising from a Member’s participation in a qualified clinical trial.

Note: Use for professional and facility outpatient claims

Table 1: Modifier Codes

Modifier Codes	Description
Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study

Table 2 contains the diagnosis code that must be reported with the primary ICD-10-CM diagnosis code consistent with the clinical trial indication.

Note: Use for professional, facility outpatient, **and/or** facility inpatient claims

Table 2: ICD-10 Code(s)

ICD-10 Code	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program

REFERENCES

1. 2010. Mar 23, The Patient Protection and Affordable Care Act (PPACA), Sec. 2709
2. Centers for Medicare and Medicaid Services. Article for Clinical Trials (A49286). Medicare Coverage Database. Accessed 6/28/2013
3. Centers for Medicare & Medicaid Services. NCD for Routine Costs in Clinical Trials. 310.1 Effective date 7/9/2007. Accessed 6/3/2013.
4. Massachusetts General Law (M.G.L), Chapter 175: Section 100L Clinical Trials; definitions; coverage. Accessed at: mass.gov
5. M.G.L. Chapter: 257 of the Acts of 2002
6. U.S. National Library of Medicine. National Institutes of Health. Clinical trial phases. Accessed at: nlm.nih.gov/services/ctphases.html
7. New Hampshire RSA § 415:18-I: Coverage Required for Qualified Clinical Trials. Accessed 10/1/2015 at: gencourt.state.nh.us/rsa/html/XXXVII/415/415-18-I.htm

APPROVAL HISTORY

October 9, 2013: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC) for an effective date of January 1, 2014.

Subsequent endorsement date(s) and changes made:

- September 17, 2014: Adopted by Tufts Health Plan – Network Health Commercial Plans and Tufts Health Plan – Network Health Medicaid Plans.
- November 19, 2014: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC), renewed without changes.
- August 12, 2015: Reviewed by IMPAC, renewed without changes
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- December 9, 2015: Reviewed by IMPAC, New Hampshire product information added for the January 1, 2016 effective date.
- March 17, 2016: Coding updated, ICD-9-CM codes removed
- September 14, 2016: Reviewed by IMPAC, renewed without changes
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- August 9, 2017: Reviewed by IMPAC, renewed without changes

- November 8, 2017: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC). Coverage Guideline updated to indicate applicability for RITogether, effective August 1, 2017
- October 10, 2018: Reviewed by IMPAC, renewed without changes
- October, 2018: Template and disclaimer updated
- March 7, 2018: Administrative update
- October 16, 2019: Reviewed by IMPAC, renewed without changes
- October 21, 2020: Reviewed by IMPAC, renewed without changes
- November 24, 2020: Fax number for Unify updated

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Medical Necessity Guidelines are developed to determine coverage for benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.

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